REMARKS

Claims 13-18, 21 and 22 are currently pending in this application. Claim 13 has been amended. Claim 22 has been cancelled. Support for the concept "temporary" can be found on page 1, lines 29-31. No new matter has been added. In view of these amendments and of the following remarks, Applicant believes that all the asserted rejections are in condition for withdrawal and all the claims are in condition for allowance.

Claims 13-18 and 21 stand rejected under 35 U.S.C. 102(b) for purported anticipation by WO 98/00148. The Examiner states that WO 98/00148 discloses the administration of creatine for the therapeutic use of improving muscle mass, function, stamina, shortening the recovery after physical strain, after post-operative muscle atrophy, treatment of heart complaints, different types of myopathy and cachectic states. The Examiner further states that WO 98/00148 discloses one dose administered three times a day for a total daily dosage of 9 g of creatine for one week, followed by a maintenance dose of 3 g of creatine in a unit dose once a day. Claim 13 has been amended to recite the administration of 5 g of creatine more than once daily during an immobilization period and only once daily during a portion of a rehabilitation period, wherein administration lasts no more than about ten weeks. WO 98/00148 neither teaches nor suggests administering creatine in the specific dosage protocol of the present invention in order to treat muscle disuse syndrome resulting from temporary immobilization.

Claims 13-18 and 21 stand rejected under 35 U.S.C. 103(a) for purported obviousness over Pischel et al. in view of Howard et al. The Examiner states that Pischel et al. teach a method of administering creatine ascorbates for enhancing muscular development and as a prophylactic against and treatment for ischemia and muscular atrophy, but does not specify a dosage wherein the amount of creatine is decreased upon treatment. Howard et al. teach administering 20-30 g creatine per day for several days and thereafter decreasing the dosage to no more than 2 to 3 g per day. Thus, the Examiner asserts that Howard et al. teach dosing with creatine until improvement is seen, and that the recitation "up to ten weeks" recited in main claim 13 includes the numerical value zero. The Examiner further asserts that differences in

dosage amounts do not impart patentability unless the criticality of those amounts are demonstrated.

Claims 13-14, 16-18 and 21-22 stand rejected under 35 U.S.C. 103(a) for purported obviousness over XP-00210314 (Wyss) in view of Howard et al. The Examiner states that Wyss teaches two creatine supplement approaches: one continuous and the other intermittent at high doses, but does not specify the creatine dose.

Claim 22 stands rejected under 35 U.S.C. 103(a) for purported obviousness over WO 98/00148. The Examiner asserts that it would be obvious to one of ordinary skill in the art to manipulate parameters such as dosage and treatment length.

The claimed invention inheres in the novel finding that a specific dosage protocol of creatine administration is able to restore muscle fibers *de novo* which have been lost, as well as the functional capacity of previously healthy muscles, as a result of temporary immobilization. Applicant agrees with the Examiner that muscle atrophy is characterized by a decrease in the size or wasting away of muscle tissue. However, muscle tissue is composed of muscle fibers, or cells, that are irreversibly lost when the muscle tissue atrophies. In other words, each muscle fiber is irreversibly lost and *de novo* muscle fibers will only be synthesized if the muscle is reused. More importantly, Applicant respectfully points out that muscle atrophy is only one of a constellation of factors that characterizes muscle disuse syndrome. Other factors include a decrease in the normal synthesis of muscle contractile enzymes, such as ATPases, and a decrease in the force of muscular contraction. Applicant submits, therefore, that muscle disuse syndrome is a distinct disorder which can be distinguished from other muscle disorders and diseases, such as muscle atrophy, muscular dystrophy, muscle ischemia, etc. Thus, the cited prior art neither teaches nor suggests the specific dosage protocol of creatine administration to treat muscle disuse syndrome in order to restore the normal functioning of previously healthy muscles suffering from muscle disuse syndrome caused by temporary immobilization.

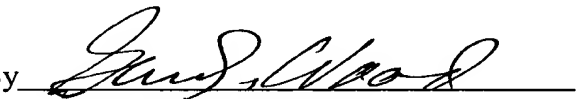
Applicant submits that amended claim 13 is proper for entry after a final office action because claim 13 now contains the limitations of cancelled claim 22, and the added

limitation "temporary" should not require further prior art searching by the Examiner. Entry and allowance of amended claim 13 is respectfully requested.

For all the foregoing reasons, amended claim 13 is patentable over the cited prior art and in condition for allowance. Withdrawal of the asserted rejections and allowance of all pending claims 13-18 and 21 are respectfully requested.

Respectfully submitted,

WEBB ZIESENHEIM LOGSDON
ORKIN & HANSON, P.C.

By 

Gwen R. Acker Wood
Registration No. 51,027
Attorney for Applicant
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com